# Guidance for Industry

# Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements

## *DRAFT GUIDANCE*

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**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**
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**DDMAC**

*Draft - Not for Implementation*

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# GUIDANCE FOR INDUSTRY[1]

# Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements



## I. INTRODUCTION

This guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure. FDA-approved patient labeling is also called *Information for the Patient*, *Patient Information*, *Medication Guide,* and *patient package inserts*.

## II. BACKGROUND

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the act) requires that advertisements for prescription drugs and biological products include a true statement of information in brief summary relating to side effects, contraindications, and effectiveness (i.e., information about the benefits and risks of using the advertised product). This is also known as the *brief summary* requirement. Generally, the display text of an advertisement discloses the product's indication and benefits. The prescription drug advertising regulations (21 CFR 202.1(e)(3)(iii)) specify that the information about risks must include *each specific side effect and contraindication* from the advertised drug's approved labeling. The regulation also specifies that the phrase *side effect and contraindication* refers to all of the categories of risk information required in the approved product labeling

[1]This guidance has been prepared by the Division of Drug Marketing, Advertising, and Communications in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

written for health professionals, including the Warnings, Precautions, and Adverse Reactions sections. Thus, every risk in an advertised drug's approved labeling must be addressed to meet these regulations.

Because the regulations do not specify how to address each risk, sponsors can use discretion in fulfilling the brief summary requirement under 202.1(e)(3)(iii). Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert, professional labeling, prescribing information, and direction circular). This labeling is written for health professionals, using medical terminology. FDA believes that this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, but may be difficult for consumers to understand.

In addition to professional labeling, some prescription drugs and biological products have FDA-approved labeling written for patients using the product. Such labeling generally contains information describing the product's risks and benefits, although some labeling describes the risks more fully than others. Generally, patient labeling does not fulfill the brief summary requirement because it does not always address "each specific" risk included in the labeling written for health professionals. Patient labeling is designed to communicate in understandable language the most important information patients need to use the product appropriately. Therefore, patient labeling focuses on the product's more serious risks and its less serious, but frequently occurring risks. Omitting less serious infrequent risks as well as those risks not likely to be caused by the product, may actually increase the usefulness of this labeling for its audience by making the more important risks clearer.

The Agency believes that approved patient labeling that comprehensively addresses the product's most serious and most common risks is a suitable means of communicating risk information to patients. Therefore, FDA does not intend to object to the use of this labeling, reprinted exactly as approved, to fulfill the requirement that DTC print advertisements contain a *brief summary* of the product's risks.[2] Such labeling generally addresses the rationale behind the law's brief summary requirement by providing benefit and risk information in a form understandable to consumers. This labeling contains the information patients are likely to find helpful in deciding whether to discuss with their health care provider the possible usefulness of the product for them. Omission of less serious infrequent events and events not likely to be drug related would not be expected to have a major effect on a patient's decision to discuss a drug with a doctor. Patients desiring more complete information can obtain it from their health care provider or by referring to labeling that is written for health care providers.

[2] This guidance does not address the use of other patient-directed prescription drug information as a brief summary for a DTC print advertisement. If a sponsor wants to use information other than the approved patient labeling, the summary would have to include *all* the risk information required by 21 CFR 202.1(e)(3)(iii).

FDA intends to object to the use of approved patient labeling as a brief summary for DTC print advertisements if the labeling *does not* comprehensively address the product's most serious and most common risks.

## III. FULFILLING THE BRIEF SUMMARY REQUIREMENT

FDA does not intend to object to the use of FDA-approved patient labeling to fulfill the brief summary requirement for DTC print advertisements if the labeling is reprinted in full and discusses in consumer-friendly language the following information from the advertised product's approved physician labeling:

- All the contraindications
- All the warnings
- All the major precautions
- All other frequently occurring side effects that are likely to be drug-related

Information from the product's approved physician labeling that need not be addressed in the FDA-approved patient labeling includes:

- Side effects that are not serious and do not occur frequently or that are unlikely to be the result of taking the product

- Information related to carcinogenesis, mutagenesis, and infertility that does not warrant a discussion under the Warnings section

- Information related to use in pregnancy that does not warrant a *D* or *X* pregnancy category

- Information related to use in labor and delivery, breast-feeding, pediatrics, and other special populations that does not warrant a discussion under the Warnings section

Some examples of products with FDA-approved patient labeling that FDA would not object to for use as a brief summary for DTC print advertisements include:

- Evista
- Fosamax
- Glucophage
- Singulair
- Tikosyn
- Xenical
- Ziagen

Some FDA-approved patient labeling focuses primarily on giving instructions for use. Other FDA-approved patient labeling focuses on a single warning. Neither of these types

of patient labeling provides the comprehensive important risk information that addresses the rationale behind the brief summary requirement. Because of the narrow focus of such labeling, FDA intends to object to its use as a brief summary for DTC print advertisements. Examples of such FDA-approved patient labeling include:

- ACE Inhibitors
- Isoproterenol inhalers